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ORIGINAL RESEARCH

Advanced Multi-Layer Watertight Closure versus Conventional Closure in Total Hip and Knee Replacement Surgery

Jana L Flener[1], Brian Po-Han Chen[2], Frank R Ernst[3], Aaron Libolt[1], Najmuddin J Gunja[2], William P Barrett[1]

[1]Proliance Orthopedic Associates, Renton, WA, USA; [2]Health Economics and Market Access, Ethicon Inc., Raritan, NJ, USA; [3]Real World Evidence and Late Phase, CTI Clinical Trial and Consulting Services, Covington, KY, USA

Correspondence: Najmuddin J Gunja, Health Economics and Market Access, 1000 US Highway 202, Raritan, NJ, 08869-1425, USA, Tel +1(908)685-2151, Email ngunja@its.jnj.com

Background: In total joint replacement procedures, surgeons have increasingly adopted advanced multi-layer, watertight closure. The objective of the study was to compare the clinical and economic outcomes for advanced multi-layer, watertight closure patients to those with conventional closure with sutures and skin staples.

Methods: Patients aged ≥18 years were included in the study if they underwent total joint arthroplasty of the hip or knee as an elective, primary, inpatient procedure between January 2014 and March 2019. Cohorts having advanced multi-layer, watertight closure or conventional closure were compared using multivariable regression analysis of surgical site infections, length of stay, operating room time, procedure time, discharge status, readmissions, reoperations, and hospital emergency department visits.

Results: A total of 1828 patients received at least one total hip or knee replacement, of which 434 (23.7%) had advanced multi-layer, watertight closure and 1394 (76.3%) had conventional closure. Unadjusted time to readmission, when occurring, was considerably longer following advanced multi-layer, watertight closure (89.9 vs 51.1 days, $p < 0.0001$), and a lower proportion of the advanced multi-layer, watertight closure cohort required reoperation within 90 days (0.0% vs 2.6%, $p < 0.0001$). Adjusted mean hospital length of stay was approximately half of a day shorter for advanced multi-layer, watertight closure patients (1.10 vs 1.65 days; $p < 0.001$), and they were also more likely to be discharged to home (Odds Ratio: 4.61; $p = 0.002$).

Conclusion: Among patients undergoing total hip and knee arthroplasty in a highly optimized real-world clinical practice, advanced multi-layer, watertight closure was associated with significantly shorter inpatient length of stay and increased likelihood of being discharged to home compared with conventional closure. These findings suggest that advanced multi-layer, watertight closure is a valuable component of an optimal workflow for total hip or knee replacement, and may be especially valuable for high-risk patients.

Keywords: wound closure, total joint arthroplasty, stratafix, dermabond prineo

Introduction

Hip and knee replacement are prevalent orthopedic surgeries, known for successfully improving mobility, ameliorating pain, and increasing quality of life. With an estimated annual incidence of more than one million in the United States (US),[1] and forecasts indicating substantial increases through 2030,[2] optimization of postoperative outcomes is crucial. Wound closure methods strongly influence rates of wound complications such as prosthetic joint infections (PJIs),[3] which are costly to treat and are among the most common reasons for revision surgeries.[4,5] Moreover, surgical site infections (SSIs) contribute significantly to emergency department (ED) visits and 30-day hospital readmissions following total hip and knee arthroplasty,[6,7] and procedural complications account for approximately half of all readmissions through 90 days.[8]

While conventional sutures and staples have been the standard for joint replacement procedures, advancements in wound closure may better facilitate rapid wound healing, enhance the cosmetic outcome, and provide improved infection

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prevention. Barbed sutures like the Stratafix™ Knotless Tissue Control Devices (Ethicon, Inc., Bridgewater, NJ, USA); can be used at various tissue layers, most of which are treated with IRGACARE® MP (triclosan) to inhibit bacterial colonization.[9,10] For superficial skin closure, 2-octyl cyanoacrylate liquid adhesive (skin glue) can be combined with a self-adhesive polyester mesh (Dermabond® Prineo®, Ethicon, Inc., Bridgewater, NJ, USA) to reinforce and share tension across a surgical incision,[11] thereby improving wound healing, patient satisfaction, cost, and infection risk in knee arthroplasty procedures.[12,13]

Several studies have demonstrated the benefits of advanced multi-layer, watertight closure with the innovative combination of barbed sutures and a skin closure system, including reductions in delayed wound healing and fewer reoperations after joint arthroplasties,[3,13] as well as fewer SSIs,[14] shorter hospital length of stay (LOS), and lower direct health care costs.[15] However, further research is needed to fully evaluate the benefits of advanced multi-layer, watertight closure (aMLWC) in total knee arthroplasty (TKA) and total hip arthroplasty (THA) procedures. As a step towards this objective, we conducted a single-center retrospective study comparing the economic and clinical outcomes of patients who underwent aMLWC versus those who received conventional closure (CC) with sutures and skin staples.

Methods

A retrospective electronic medical record review was conducted to evaluate the outcomes of patients receiving TKA or THA. We identified consecutive procedures performed by the senior author, who primarily used CC between 2014 and 2017, then adopted a regular and consistent approach of aMLWC starting in January 2018. Surgical preparation and technique prior to closure remained unchanged throughout the study duration.

In order to achieve optimal multi-layer, watertight closure following total knee replacement, the surgical team began by placing the knee in approximately 30 to 40 degrees of flexion. Two number 1 Vicryl™ sutures were placed with one proximal and the other distal to the patella to align the fascia for closure. This was followed by closure of the joint capsule using 1–0 STRATAFIX™ Symmetric PDS™ Plus, subcutaneous closure with unidirectional 2–0 STRATAFIX™ Spiral PDS™ Plus, and subcuticular closure with 4–0 unidirectional STRATAFIX™ Spiral PDS™ Plus (Figure 1). The knee was then placed into full flexion for careful application of the self-adhering mesh to approximate the skin tissue. To complete the procedure, a layer of liquid adhesive was carefully applied to the adhesive mesh.

Following a total hip replacement procedure, the joint capsule was sutured using number 1STRATAFIX™ Symmetric PDS™ Plus. Three interrupted size 3–0 Vicryl™ sutures were then used to approximate the arthrotomy edge, with one each at the proximal and distal apex and one at the center. A size 3–0 STRATAFIX™ Spiral PDS™ Plus was used for

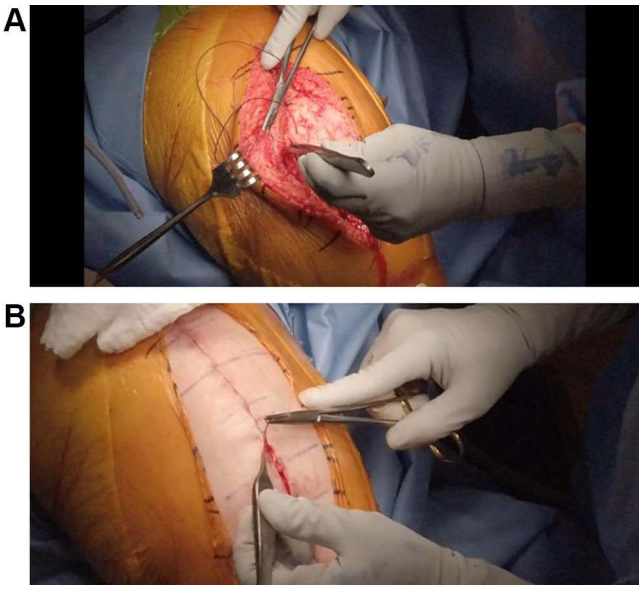

Figure 1 Depiction of advanced multi-layer watertight closure. (**A**) Fascial closure with Stratafix Symmetric. (**B**) Skin closure with Stratafix Spiral.

subcutaneous closure, followed by size 4–0 unidirectional STRATAFIX™ Spiral PDS™ Plus for the subcuticular layer and the polyester mesh with liquid adhesive for skin closure.

In conventional wound closure cases, the surgical team began by placing the knee in approximately 30 to 40 degrees of flexion. Number 1 Vicryl™ was used at the fascial layer for interrupted closure of the joint capsule. Subcutaneous closure was then performed with 2–0 undyed Vicryl™ and an interrupted technique, followed by subcuticular closure with surgical staples. The wound was dressed with Xeroform™, fluff dressings and ABD pads held in place with a 4-inch ACE™ bandage.

Data Source

Following approval of the study by the Research Oversight Committee and a waiver of HIPAA authorization by the Western Institutional Review Board, existing patient-level clinical and economic data were provided by a single US medical center affiliated with a nearby university and an associated orthopedic surgery practice.

The data collected from electronic medical records included baseline patient characteristics of age, race, sex, body mass index (BMI), smoking status, type of procedure, and discharge disposition. Outcomes of interest included LOS, operating room time, procedure time, reoperations, ED visits within 30 days, readmissions, and changes from the first to last post-surgical patient-reported pain score prior to discharge.

Study Population

Patients were included in the study if they underwent total joint replacement of the hip or knee as an elective primary procedure during an inpatient admission between January 1, 2014, and March 31, 2019, at the study site. Patients were required to be ≥18 years of age with a minimum of one year of post-surgery follow-up information. Patients were excluded if their records missing key data elements required for the pre-planned analyses, including patient demographics or outcomes of interest.

Statistical Analysis

Descriptive analyses reported baseline characteristics and outcomes of interest separately for the aMLWC and CC cohorts. Continuous variables were compared across cohorts using t-tests, while categorical variables were compared using Fisher's exact. In addition, Log rank tests were used to compare Kaplan–Meier survival between cohorts for reoperation within one year, readmission within 90 days, and an ED visit within 30 days after TKA or THA.

Multivariable regression models were used to determine the effect of wound closure cohort on key outcomes while adjusting for potential confounders. Logistic regression was used to model the occurrence of SSIs within 30 or 90 days, hospital readmissions within 30 or 90 days, and ED visits within 30 days. Firth logistic regression was used to model discharge-to-home status in order to avoid potential data separation and the resulting bias related to the small number of non-home discharges.[16] Hospital LOS, in days, was modeled using Poisson regression, with stays categorized as 1, 2, or ≥3 days due to very few hospital stays of >3 days.

Operating room time and procedure time, in minutes, as well as change in pain score, were modeled using linear regression, while Cox proportional hazards models were used to model survival from reoperation, readmission, and ED visit. Firth's penalized likelihood was used to enable model convergence for reoperation due to the lack of events in one cohort. Patients without recorded events were censored as of the end of the time frame, but not for any loss due to follow-up or death occurring before the end of the time frame. The following covariates were included in all models, except where excluded due to data separation or collinearity between the procedure type and the covariate: age, gender, BMI, smoking status, TKA vs THA, discharge status.

Results

Patient and Procedure Characteristics

The study included 1828 patients with at least one TKA or THA procedure between January 1, 2014, and March 31, 2019 (Table 1). Of these, 434 (23.7%) had aMLWC and 1394 (76.3%) had CC at the time of their first study procedure.

Table 1 Patient and Procedure Characteristics

	CC N=1394	aMLWC N=434	P-value
Discharge year for 1st surgery			<0.0001
2014	397 (28.5%)	0 (0%)	
2015	249 (17.9%)	0 (0%)	
2016	399 (28.6%)	0 (0%)	
2017	349 (25%)	0 (0%)	
2018	0 (0%)	358 (82.5%)	
2019	0 (0%)	76 (17.5%)	
Female	722 (51.8%)	224 (51.6%)	0.9476
Age, years	64.2 ± 9.6	65.7 ± 9.4	0.0032
Race			0.0025
American Indian, Alaska Native	4 (0.3%)	2 (0.5%)	
Asian	39 (2.8%)	21 (4.8%)	
Black or African American	33 (2.4%)	11 (2.5%)	
Native Hawaiian, Pacific Islander	1 (0.1%)	5 (1.2%)	
White	1286 (92.3%)	381 (87.8%)	
Other Race	31 (2.2%)	14 (3.2%)	
Smoker	43 (3.1%)	9 (2.1%)	0.2686
Body mass index	29.2 ± 4.9	29.5 ± 4.8	0.2982
Distinct procedures	1554 (100%)	553 (100%)	0.0227
Total Hip Arthroplasty	716 (46.1%)	286 (51.7%)	
Total Knee Arthroplasty	838 (53.9%)	267 (48.3%)	

Notes: Some patients had more than one joint procedure. Patient characteristics are at first procedure. Two-sided *p*-values are based on a chi-square test for categorical variables and an independent *t*-test for continuous variables.
Abbreviations: CC, conventional closure; aMLWC, advanced multi-layer watertight closure.

Approximately 52% were female, 2–3% of patients were reported to be smokers, and mean BMI was approximately 29. Patients with aMLWC used in their first study procedure were approximately 1.5 years older (65.7 vs 64.2, $p = 0.0032$).

There were 2107 distinct study procedures, 553 (26.2%) using aMLWC and 1554 (73.8%) using CC, with patients represented more than once if they had multiple joints replaced that each met study inclusion criteria (Table 2). THA

Table 2 Unadjusted Analysis of Outcomes

Outcome	CC N=1554	aMLWC N=553	P-value
SSI within 30 days	5 (0.3%)	4 (0.7%)	0.2535
SSI within 90 days	7 (0.5%)	5 (0.9%)	0.3196
Discharged to home	1488 (95.8%)	544 (98.4%)	0.0038
Reoperation within 365 days	37 (2.4%)	0 (0.0%)	<0.0001
Readmission within 30 days	29 (1.9%)	7 (1.3%)	0.4459
Readmission within 90 days	38 (2.4%)	11 (2.0%)	0.6242
Time to readmission, days (N= 52 CC, 24 aMLWC)[a]	51.1 (52.3)	89.9 (63.2)	0.0062
ED visit within 30 days	48 (3.1%)	14 (2.5%)	0.5607
Time to first ED visit, days (N= 48 CC, 14 aMLWC)[a]	7.8 (5.4)	10.2 (7.8)	0.1903
Length of stay, days	1.7 (0.7)	1.1 (0.4)	<0.0001
Procedure time, minutes	87.2 (19.1)	87.0 (15.0)	0.8596
Operating room time, minutes	133.9 (21.2)	134.8 (17.1)	0.2830
Change in pain score	0.74 (2.7)	0.50 (2.6)	0.1106

Notes: Results are expressed as n (%) for categorical outcomes and mean (standard deviation) for continuous outcomes. P-values are based on Fisher's exact test for counts and independent t-tests for continuous variables, using the Satterthwaite correction if equality of variance was rejected at alpha=0.05. [a]Comparison is between cases with occurrence only.
Abbreviations: CC, conventional closure; aMLWC, advanced multi-layer watertight closure; SSI, surgical site infection; ED, emergency department.

procedures represented 46.1% of the CC procedures compared to 51.7% of the aMLWC procedures, with the remainder being TKA ($p = 0.0227$).

Unadjusted Analysis

A higher proportion of aMLWC patients were discharged home following their hip or knee replacements than CC patients (98.4% aMLWC vs 95.8% CC, $p = 0.0038$) (Table 2). The mean LOS was also shorter for aMLWC patients (1.1 days vs 1.7 days, $p < 0.0001$), with a larger difference in the subset of procedures completed in the afternoon (1.1 days for aMLWC vs 1.8 days for CC, $p < 0.0001$) versus those completed in the morning (1.1 days for aMLWC vs 1.5 days for CC, $p < 0.0001$).

Despite similar all-cause readmission rates within 90 days ($p = 0.5410$), the mean time to readmission was almost 40 days longer for the 2.0% of aMLWC patients who were readmitted than for the 2.4% of CC patients who were readmitted (89.9 ± 63.2 days for n = 24 patients vs 51.1 ± 52.3 days for n = 52 patients, $p = 0.0062$). No other outcomes were found to be significantly different (Table 2).

Kaplan–Meier plots were also constructed to compare the rates of survival over time from reoperation within a year after joint replacement ($p = 0.0003$), readmission within 90 days ($p = 0.5370$) and ED visits within 30 days ($p = 0.5038$) (Figure 2).

Multivariable (Adjusted) Analysis Results

All statistical models are summarized by type in Table 3. Outcomes that were significantly improved for procedures using aMLWC versus CC, after adjusting for key patient and surgery characteristics, were reoperation, length of stay, and discharge to home. The remainder of the modeled outcomes were not significantly different between the two cohorts. The adjusted hazard ratio for reoperation within a year was quite low for procedures that used aMLWC (HR: 0.03 [0.00, 0.51], $p = 0.0147$), while the adjusted mean LOS of the index admission was shorter by approximately 33% (1.10 vs 1.65 days, $p < 0.0001$, Figure 3). Patients were significantly more likely to be discharged to home versus non-home settings of care in the aMLWC group versus the CC group (OR: 4.61, 95% CI 1.78–11.94; $p = 0.0016$).

Discussion

This is one of the first studies to evaluate the clinical and utilization outcomes of aMLWC in elective inpatient TKA or THA procedures. In 2107 joint replacements performed by a single surgeon at a single center, aMLWC was associated with significantly fewer reoperations, shorter LOS and increased likelihood of discharge to home compared with CC after adjusting for important covariates.

Though several studies have reported on the advantages of aMLWC or of various components of aMLWC, there remains little evidence directly comparing a standardized closure method with conventional Methods. A recent systematic literature review of high-quality TKA and THA procedures concluded that significant variability exists with respect to wound closure methods, but that aMLWC may reduce complications and healthcare costs.[17] However, the authors note that the methods reported were substantially heterogeneous, as were definitions of key outcomes. Consequently, it is difficult to make comparisons among studies.

A review by Snyder et al discussed the implementation of integrated clinical pathways incorporating multi-layer watertight closure, reporting that they have reduced the total per-episode cost of care by more than 20%, which was driven by shortened LOS, reduced readmissions, and post-acute care minimization.[14] In addition, Vendittoli et al found that their enhanced recovery after surgery (ERAS) short-stay protocol, incorporating multi-layer watertight closure, was associated with a significantly lower rate of Grade 1 and 2 complications compared to standard care (0.8 vs 3.0 per patient, $p < 0.001$).[15] The mean LOS in the ERAS group decreased by 2.8 days for THA procedures (0.1 vs 2.9 days, $p < 0.001$) and 3.9 days for TKA (1.0 vs 4.9 days, $p < 0.001$). The mean estimated direct healthcare cost reduction under the ERAS protocol was 1489 Canadian dollars (CAD) per THA and 158 CAD per TKA.[15]

In the present study, the 365-day reoperation rate was lower (0.0% vs 2.4%) and the time to readmission was longer (89.9 days vs 51.1 days) for aMLWC patients in the subset of patients who had readmissions. These outcomes have a direct impact on the 90-day bundled payments for total joint arthroplasty procedures, making them relevant to both the

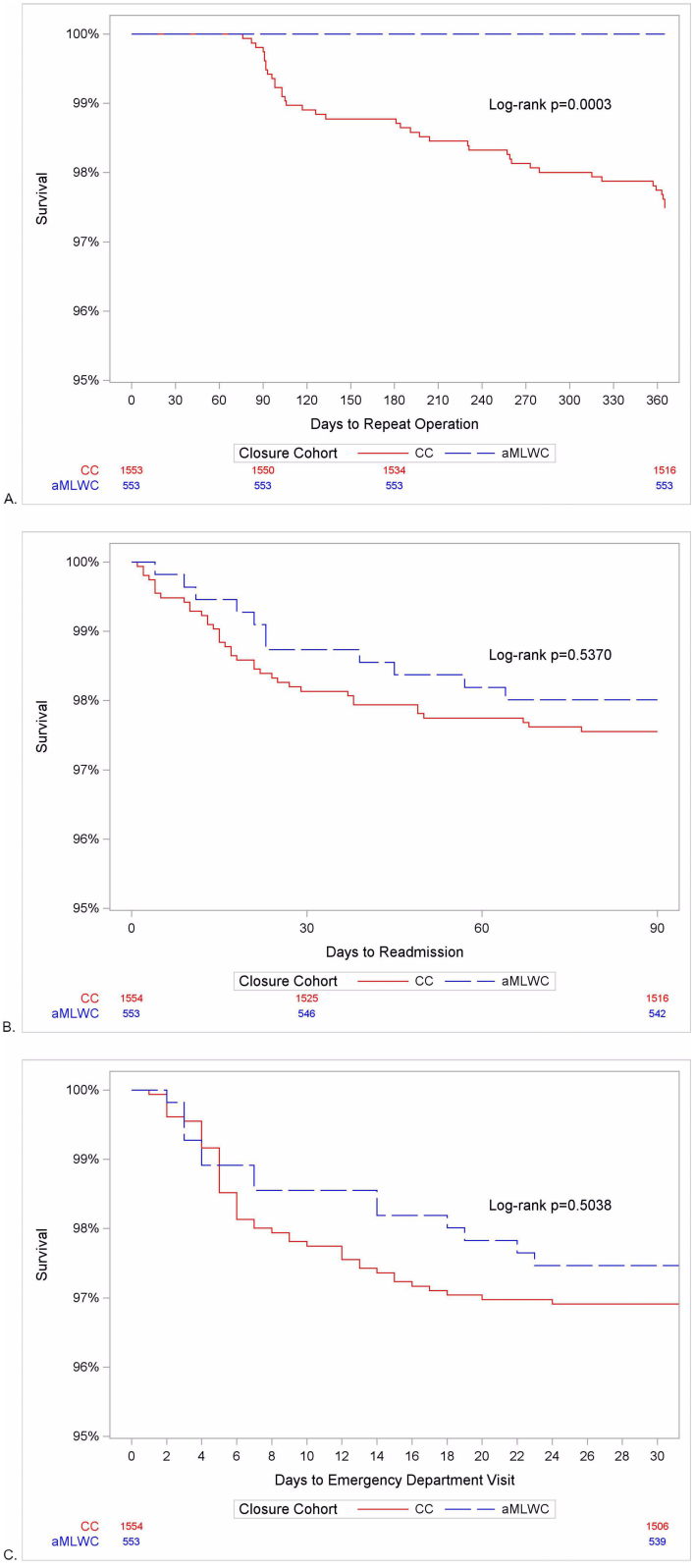

Figure 2 Kaplan Meier analysis for reoperation, readmission, Emergency Department visit. (**A**) Reoperation by closure cohort. (**B**) Readmission by closure cohort. (**C**) Emergency Department visit by closure cohort.

Table 3 Multivariable Model Results

Logistic Regression Outcome	**Odds Ratio (95% CI) aMLWC vs CC**	***P*-value**
SSI within 30 days	1.75 (0.46, 6.64)	0.4127
SSI within 90 days	1.67 (0.52, 5.36)	0.3892
Readmission within 30 days	0.63 (0.27, 1.46)	0.2782
Readmission within 90 days	0.77 (0.39, 1.53)	0.4538
Discharge to Home	4.61 (1.78–11.94)	0.0016
ED visit within 30 days	0.79 (0.43, 1.45)	0.4466
Cox Regression Outcome	**Hazard Ratio (95% CI) aMLWC vs CC**	***P*-value**
Reoperation within 365 days	0.03 (0.00, 0.51)	0.0147
Readmission within 30 days	0.63 (0.27, 1.45)	0.2773
Readmission within 90 days	0.77 (0.39, 1.52)	0.4490
ED visit within 30 days	0.79 (0.44, 1.45)	0.4514
Outcome	**Adjusted Outcome Estimates: aMLWC vs CC**	***P*-value**
Length of Stay, days	1.10 vs.1.65	<0.0001
Procedure time, minutes	87.2 vs 86.8	0.6657
Operating room time, minutes	135.2 vs 133.6	0.0967
Change in pain score, points	0.70 vs 0.95	0.0941

Abbreviations: SSI, surgical site infection; aMLWC, advanced multi-layer watertight closure; CC, conventional closure; ED, Emergency department; CI, confidence interval.

payer and provider. Although we are unable to directly attribute improved outcomes to the adoption of aMLWC, the watertight closure across multiple tissue layers with a barbed knotless tissue control device and the comparatively greater strength and unique antimicrobial barrier of mesh combined with a liquid adhesive represent a potential solution to

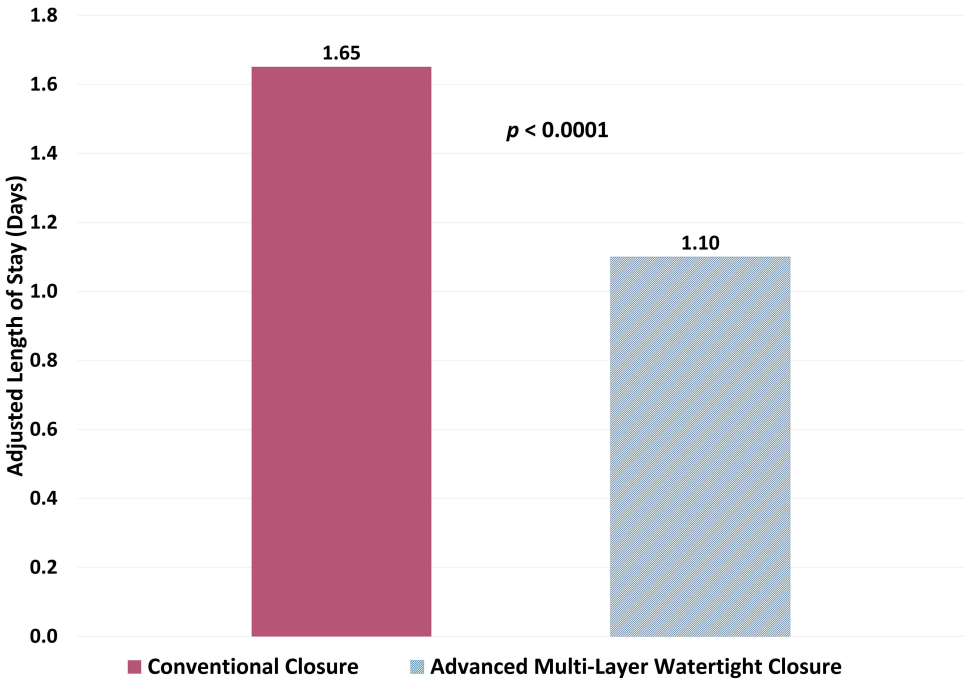

Figure 3 Adjusted mean length of stay for conventional closure versus advanced multi-layer watertight closure procedures.
Notes: Models were adjusted for age, gender, body mass index, hip vs knee procedure, and smoking status.

wound complications such as dehiscence and drainage, which provide a retrograde infection pathway.[18] In the present study, wound dehiscence was not reported as a reason for any of the ED visits or hospital readmissions. Furthermore, recent studies by Anderson et al and Herndon et al have shown that combined with barbed sutures used for closure of deep layers, polyester mesh was associated with fewer episodes of delayed wound healing and reoperations than the standard wound dressing.[3,13] The authors pointed out that the possible mechanism may have been a more even distribution of wound tension. In addition, since it remains in place longer during the postoperative period, the prolonged support of the wound edge could be a driving factor.

We observed that aMLWC was associated with more efficient arthroplasty care, as demonstrated by greater likelihood of being discharged to home (OR = 4.61 [1.96–13.60]; $p = 0.002$) and shorter LOS (1.10 days vs 1.65 days; $p < 0.001$) than CC. In our study, all patients stayed at least one night following their surgery. However, the effect of aMLWC on LOS may be an economically significant consideration for providers who are transitioning elective joint arthroplasty to ambulatory surgery centers and outpatient programs as a culmination of advances made over the past two decades.[19] Our findings were also aligned with another US study by Tan et al, which similarly showed that the implementation of aMLWC was associated with an improvement in LOS and discharge status compared to conventional closure, even after controlling for pre-existing underlying short- and long-term trends.[20]

As a contributor to the improved LOS, readmissions, and reoperation outcomes, the relatively low rate of SSIs (<1% of patients) and readmission rates (2–2.5% within 90 days) in the present study may be a result of the comprehensive optimization efforts by the study surgeon. Moreover, preoperative patient optimization has been shown to play a significant role in successful joint arthroplasties.[21,22]

Several retrospective database studies of individual components of multi-layer watertight closure in joint arthroplasty have also reported results that are similar to those seen in the present study. A study of >20,000 matched patients undergoing hip or knee arthroplasty in the Premier Hospital Database found shorter LOS, lower OR time, and a lower rate of discharge to skilled nursing or other non-home settings in the cohort with Stratafix barbed sutures compared to the cohort with conventional sutures only.[23] In a similar study, Sutton et al compared the Dermabond Prineo skin closure system with skin staples in 1942 propensity-matched patients undergoing TKA,[24] finding that polyester mesh tape with liquid adhesive was associated with shorter LOS (2.8 vs 3.2 days), >12% lower rate of non-home discharge, and fewer readmissions through 30, 60, or 90 days compared to skin staples.

Another advantage of aMLWC is that it allows a reduction in follow-up office visits due to eliminating the need for skin staple removal or dressing changes. This advantage, along with the reductions in LOS and non-home discharge, was highlighted in the guidelines developed by the International Consensus Group for resuming elective orthopedic surgery during the SARS-CoV-2 pandemic.[25] Specific recommendations that align with these results include the following: (1) the use of suture material (such as staples and nonabsorbable sutures) that require a return office visit should be minimized, and the wound should be covered in an occlusive dressing; (2) the length of hospital stay for patients should be minimized; (3) patients should be discharged home, with transfers to inpatient rehabilitation minimized; (4) post-discharge office visits should be minimized and limited to patients experiencing issues or complications, with most follow-up occurring via telemedicine.

Limitations

As with prior studies of wound closure methods, this study has limitations related to the source data and the retrospective study design. Certain previously reported advantages of aMLWC (eg, improved cosmesis, dehiscence not leading to ED visit or readmission, and a reduction in delayed wound healing) could not be studied because the information was not available in the electronic health records. Nor was there sufficient detail in the data to a clinical link between the reported outcomes and the wound closure. In addition, since the population represented a convenience sample from a single site and operator, the generalizability of the study results may be limited. Though the population was limited to procedures performed by a single operator to ensure standard methodology across procedures, the timing of cases (ie, operation dates) using aMLWC vs CC methods was different, which may have introduced unmeasured confounders. For example, shifting practice trends and/or other improvements in surgical workflow may have contributed to the improvements seen with aMLWC. In addition, as with most previous studies, causality cannot be established for the observed outcomes due

to the observational nature of the study. For these reasons, our results should be considered exploratory, and a well-designed randomized controlled trial will be required to validate their clinical significance.

Conclusion

Among patients undergoing total hip or knee arthroplasty in a highly optimized real-world clinical practice, aMLWC was associated with a reduction in reoperations, shorter adjusted inpatient LOS, and an increase in the adjusted likelihood of being discharged to home compared with CC using sutures and skin staples. These findings suggest that adopting aMLWC as a part of an optimized workflow for total hip and total knee replacements could provide valuable benefits to both patients and hospitals. Prospective studies are needed to confirm these findings.

Abbreviations

aMLWC, Advanced multi-layer; watertight closure; BMI, Body mass index; CC, Conventional closure; ED, Emergency Department; ERAS, Enhanced recovery after surgery; HR, Hazard ratio; LOS, Length of stay; OR, Operating room; PJI, Prosthetic joint infection; SSI, Surgical site infection; THA, Total hip arthroplasty; TKA, Total knee arthroplasty.

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